Food Additive Rules Remain Subjectiv

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WASHINGTON—One of the first scientific issues faced by the fledgling Food and Drug Administration, soon after the turn of the century, was the safety of the artificial sweetener, saccharin. The substance was branded a hazard by the first FDA chief, the outspoken Harvey Wiley, a Government scientist whose campaign for pure food had helped create the FDA.

But President Theodore Roosevelt, a corpulent man who took saccharin on doctor's orders, demurred and directed that an outside committee review the issue. The committee gave the chemical a clean bill of health, although the actual evidence one way or the other was scanty.

Over the years, scientists have continued to study saccharin, but despite the explosive growth of scientific technology and the increasing sophistication of laboratory tests, the basic issue of its safety is not yet completely resolved. This was apparent recently when another scientific panel concluded that saccharin was safe "on the basis of available information" but urged that more research be conducted, because previous safety tests were not up to current standards.

Modern science poses similar difficulties in assessing the safety of many other food additives. The main problem: As laboratory tests become more subtle and sophisticated, their significance often becomes increasingly obscure.

Things were simpler in Harvey Wiley's day. Only a few chemicals were being added to foods then and only the grossest measurements of their biological effects could be made. Dr. Wiley's procedure was to monitor the diets of a handful of willing subordinates, his so-called "poison squad," and observe their medical reactions.

But now, when a food additive safety issue arises, like that of saccharin, the FDA's reactions follow a familiar pattern. The agency first turns for help to scientists in the prestigious National Academy of Sciences-National Research Council, which prides itself on careful surveillance of potential food hazards. After lengthy study, these non-government scientists usually render an exhaustive, but ambiguous report, passing the buck right back to FDA.

And Government regulators find themselves caught between consumer advocates who want additives banned if the tests reveal any hint of hazard, and food industry officials who argue that with enough ingenuity almost any substance can be "proven" harmful in laboratory experiments.

Both arguments are now being pressed in scientific debate over the wisdom of a now-famous 1958 amendment to the food and drug law. Originally sponsored by Rep. James J. Delaney (D., N.Y.), the amendment bans food additives shown to cause cancer if fed to laboratory animals.

It was this arbitrary requirement, not reasoned scientific judgment, that required FDA restrictions on cyclamates, former HEW Secretary Robert Finch complained last year. Mr. Finch subsequently urged that the amendment be modified to allow the FDA to set safe levels for human use of essential food additives, even if these did sometimes produce cancer in test animals.

But FDA critics, including some politicians on Capitol Hill, are pushing for just the opposite. They want the Delaney amendment broadened to require an FDA ban if other food hazards, such as birth deformities, turn up in animal testing.

The food industry and many scientists are vigorously promoting the Finch approach. The industry argues that the amendment is already so restrictive it's unworkable, and that it would ban many useful substances if rigidly interpreted and widely applied. "I'm utterly convinced after 30 years in the business that given enough time I can produce cancer with almost any chemical," insists Lloyd Hazleton, director for life sciences of Hazleton Laboratories Inc., a subsidiary of TRW Inc. and a leading laboratory testing firm.

It would be easier to apply the amendment if only a handful of cancer causing chemicals, like the coal tar dyes, were known. But when diligent laboratory testing turns up many more compounds, including DDT, that produce cancer, the social calculations become far more complicated. Some of these chemicals are ubiquitously distributed in the environment and find their way into foods, although in trace amounts—a few parts per billion—compared to the concentrations tested in animals.

A strict application of the amendment could ban foods with even these tiny amounts of such chemicals. Indeed, just before Thanksgiving 1959, then HEW Secretary Arthur Flemming didn't hesitate to seize the year's cranberry crop on the ground that it was contaminated with the cancer-producing weed-killer, aminotriazole. The Nixon Administration, eager to avoid such complications, now insists that this policy, "adopted for a different situation by a prior Secretary, is obviously not legally binding on his successors."

The major uncertainty underlying the debate over the Delaney amendment is whether a "threshold" exists below which an otherwise hazardous compound can be as be safe for humans. Some scientists one molecule could be harmful, whi insist safe tolerances can be est "We've got to find out," insists Dale FDA associate commissioner for sci the laboratory tests needed to sati answer the threshold question for l clamates and other suspect substan be prohibitively expensive, costing as $100 million.

Consumer critics like Ralph N mounting a major attack on Federal tection policies, and contend that the amendment is essential to force hesit regulators to act. There is evidence conclusion. For several years, the FI tific staff insisted that cyclamate stricted because of evidence that t duced birth deformities and genetic in animals. FDA officials weren't i by these findings and acted only cancer data developed; many medi still think the other hazards are mor cant.

Delaney amendment proponents amendment's application should be e not restricted. "We simply must practice of allowing food manufact use the unknowing consumer as p large-scale trial in the testing of fo tives that have not been required to quate laboratory examination," decl Gaylord Nelson (D., Wis.). He has pr bill embodying this philosophy.

But which tests should be relied how can scientists be certain their using animals are relevant to human Medical men, for example, are de cerned about the evidence that som cals are capable of breaking chro the carriers of human hereditary These abnormalities could be medi nificant, increasing the incidence o retardation and other diseases in fu erations. Or they could be laboratory unrelated to human disease.

Similarly, medical men have been ingly aware of the potential of chem causing birth defects, but there is c ble debate over the appropriateness developed laboratory tests.

Whatever the arguments for toug softening the Delaney amendment, t is making little headway in Congr simple anti-cancer ban has a powe tional appeal that preserves it politic change in any way.

And it seems clear that while th of food testing has come a long w Harvey Wiley's day, its application t is still as subjective as ever.